Santhera Pharmaceuticals (SIX: SANN) is a Swiss specialty pharmaceutical company focused on the development and commercialisation of innovative pharmaceutical products for the treatment of orphan mitochondrial and neuromuscular diseases.

In September 2015, our leading product Raxone® (idebenone) received European Marketing Authorisation in the treatment of patients with LHON (Leber's Hereditary Optic Neuropathy). Raxone® is not only the first and only medicine approved for this condition, but it is also the first medicine approved for any mitochondrial disorder.
The company is currently developing Raxone® in other areas of high unmet medical needs, like the treatment of Duchenne Muscular Dystrophy (DMD) and Primary Progressive Multiple Sclerosis (PPMS). In addition, Santhera's pipeline includes omigapil, an investigational drug with anti-apoptotic properties, a compound in development to address unmet medical needs for patients with Congenital Muscular Dystrophy (CMD).

For more information, please visit the company's website www.santhera.com

We are currently looking to hire a:

Pharmacovigilance Quality, Training & Compliance Manager

to be based at our HQ in Liestal, Switzerland

Scope of Work

The Pharmacovigilance Quality, Training & Compliance Manager is a business area expert supporting the Head of Safety and Pharmacovigilance and the European Qualified Person for Pharmacovigilance in establishing procedures and processes to ensure the overall compliance of the company-wide pharmacovigilance system with Santhera's legal PV obligations both as Marketing Authorization Holder and Sponsor of clinical trials.

In particular this is achieved by developing and delivering PV specific training for Santhera personnel and key vendors; developing and maintaining systems to oversee and track compliance with pharmacovigilance regulatory requirements globally, including oversight of system performance, assurance that adequate CAPA plans are installed where needed and are timely completed; provide support to the development of written procedures to ensure that the PV system is compliant with governing regulations and adequately described in Quality Management System documents.

The responsibilities for this role include the following:

- Perform regular gap analysis of the Santhera global pharmacovigilance system to ensure ongoing compliance with regulatory pharmacovigilance requirements globally. Prepare proposals for the development of new company (PV specific and other) procedures or IT systems, or for changes in existing ones as needed.
- Where gaps in the quality management system exist or updates are needed, ensure continued compliance with global regulatory pharmacovigilance requirements. In cooperation with Santhera's Quality Department also author new pharmacovigilance procedures or updates thereof, ensure their timely release, related training requirements and their implementation.
- Ensure oversight of the applied PV procedures and standards at individual country level, develop and maintain local safety agreements with HQ in cooperation with local management and PV responsible staff; ensure CAPAs are put in place where needed and are executed.
- Build systems (procedural and electronic) to facilitate oversight by the Head of Drug Safety and Pharmacovigilance and by the European Qualified Person of the PV system and its functioning and for monitoring ongoing compliance with all applicable regulatory pharmacovigilance requirements globally. Develop additional KPIs where needed to ensure proper overview of the system's performance.
- Support the preparation for and management of PV related audits (internal and of key Santhera vendors and business partners) and Authority inspections. Participate in such audits as auditor as needed and provide support to pharmacovigilance inspections; participate as interviewee in such

inspections as needed. Provide input in Santhera's annual PV Audit Plan and ensure ad-hoc updates are made should these become needed.

- Receive and review reports on internal and external PV specific and non-PV specific local, regional and global audits and inspections and identify areas needing corrective and/or preventive actions. Ensure adequate root cause analysis is available and well documented to cover pharmacovigilance aspects and their proper presentation in the PSMF, including their status. Maintain the audit trail of CAPA plans with PV relevance and create living overview of their status of executional progression and completion. Signal overdue CAPAs or CAPAs at risk to the Head of Drug Safety and Pharmacovigilance and European Qualified Person for Pharmacovigilance.
- Advise on role specific training matrices for Santhera personnel from a pharmacovigilance perspective. Ensure proof is available of adequate and continued fulfilment of PV training requirements for all Santhera Personnel. Deliver PV training to Santhera Personnel and, on request also to service providers (Santhera vendors) and business partners.
- Provide input into PV requirements and clauses necessary to be included in contracts with service providers (Santhera vendors) for PV specific and other services (for instance vendors to whom management of PSP is potentially outsourced or who are supporting Market Research, social media screening projects or other), as well as in contracts with business partners and investigators in investigator sponsored clinical trials that are supported by Santhera. Ensure that a living overview of such contracts is available to PV and monitor compliance of the third parties with the clauses in the contracts, propose corrective or preventive actions where needed to restore compliance or assure continued compliance.
- Support the Head of Drug Safety and Pharmacovigilance and the EU QP PV in the monitoring of changes and new developments in the regulatory pharmacovigilance requirements globally. Provide support in signalling, assessing and implementing the potential impact of such changes and new developments on Santhera's PV system.

Required background and experience:

- Relevant life sciences degree (such as nurse, biology, pharmacy)
- Minimum 3 years of experience in a similar position in a pharmaceutical company or CRO
- Advanced knowledge of the relevant pharmacovigilance regulations such as GVPs at European level and relevant knowledge of US regulations
- Good project management skills, be oriented to detail and committed to provide deliverables within agreed timelines
- Ideally previous experience in multicultural environment and matrix organizations

Required competencies and skills:

- Excellent communication and presentation skills
- Excellent interpersonal and networking skills
- Team player, collaborative attitude
- Self-motivation, able to work independently as well as on cross-functional teams
- Personal resilience, perseverance, energy and drive
- Fluency (spoken and written) in English

If you are interested to apply for this role, please send your CV and motivation letter by email to:
career@santhera.com

Strictly no agencies

Recruitment agencies are kindly invited to refrain from sending to Santhera unsolicited CVs.